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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,958	05/10/2006	Nalin M. Kumar	UIC0005US.NP	2671
26250 7590 08/11/2008 LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053				
EXAMINER MCGARRY, SEAN				
ART UNIT 1635		PAPER NUMBER		
NOTIFICATION DATE 08/11/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

### Office Action Summary

**Application No.**

10/567,958

**Applicant(s)**

KUMAR ET AL.

**Examiner**

Sean R. McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-20 is/are pending in the application.  
4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 12-14 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SE/IB)  
Paper No(s)/Mail Date 4/7/06, 5/18/06, 1/29/07, 3/24/08  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 12-14 in the reply filed on 7/23/08 is acknowledged. The traversal is on the ground(s) that there would be no search burden to examine both Groups I and II. This is not found persuasive because of the reasons set forth in the restriction requirement. Applicant has not provided any reasons that would show the reasons set forth in the restriction requirement were in error.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/23/08.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by McSWIGGEN et al [WO 03/070197]. It is noted that at least the priority documents for McSwiggen et al, 60/363,124 and 60/425,559, provide support for the subject matter relied upon in the McSwiggen document.

McSwiggen et al have disclosed siRNA targeted to human TGFBR11 including those within the size range instantly recited (See Table 1, Table II, the abstract and the entirety of the specification). [SEQ ID NO: 159 of the instant application is the mRNA sequence of human TGFBR11]. McSwiggen et al disclose the use of pharmaceutical carriers and pharmaceutical compositions comprising siRNA targeted to human TGFBR11 for the treatment of various conditions associated with TGFBR11 (see pages 43 and 81-90, for example).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over McSwiggen et al [WO 03/070197] and MURRAY et al [US 20030064944].

McSwiggen et al have disclosed siRNA targeted to human TGFBR2 including those within the size range instantly recited (See Table 1, Table II, the abstract and the entirety of the specification). [SEQ ID NO: 159 of the instant application is the mRNA sequence of human TGFBR2]. McSwiggen et al disclose the use of pharmaceutical carriers and pharmaceutical compositions comprising siRNA targeted to human TGFBR2 for the treatment of various conditions associated with TGFBR2 (see pages 43 and 81-90, for example). McSwiggen et al do not specifically disclose the use of a "wound healing agent" in their pharmaceutical compositions comprising siRNA targeted to TGFBR2.

MURRAY et al have taught the use of antisense compounds which, as does siRNA, inhibit gene expression of a targeted gene. Murray et al have taught the use of antisense compounds to inhibit expression of human TGFBR2 for the purpose of treating disease associated with TGFBR2 (See paragraphs 27, 33, 58, and 60, for example). It has been taught by Murray et al to use 5-fluorouracil (see paragraph 126,

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for example) in compositions comprising antisense compounds to inhibit TGFBR11 in methods of treating disease associated with TGFBR11. It is noted that applicant specification, at page 5, specifically defines 5-fluorouracil as a "wound healing" agent.

One in the art would clearly have taken the two references together and realized that the composition of Murray et al could easily have been supplemented with siRNA targeted to TGFBR11 or that an antisense targeted to TGFBR11 could have substituted for an antisense compound since it was known in the art at the time of invention that both compound function to inhibit expression of a gene target and further since it was known in the art at the time of invention that siRNA often provides for inhibition that is superior to that of antisense compounds.

The invention as a whole would therefore have been prima facie obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry  
Primary Examiner  
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